



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,543	04/14/2000	EUGEN SCHWARZ	MERCK-2084	3926

23599 7590 02/26/2002

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

[REDACTED] EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	17

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 16

Application Number: 09/529,543

Filing Date: 04/14/00

Appellant(s): SCHWARZ et al.

James E. Ruland
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 11/20/01.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

Art Unit: 1615

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

Claims 1-9, and 11-20 are rejected.

Claim 10 is allowed.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-20 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

I. Claims 1-9, and 12-20;

II. Claims 10 and 11.

(8) *ClaimsAppealed*

Art Unit: 1615

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5536526	Virtanen et al.	07/1996
5204115	Olinger et al.	04/1993
5958471	Schwarz et al.	09/1999
5576014	Mizumoto et al.	11/1996

(10) *Grounds of Rejection*

1. Claims 1-5, 9, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen et al. US 5,536,526.

Virtanen teaches a composition comprising about 94% to 98% by weight of xylitol, less than about 1% by weight of water, and about 1% to about 5% by weight of acceptable polyol other than xylitol, e.g., mannitol, lactitol, sorbitol, maltitol and isomalt (column 5, lines 39-53). The composition can be prepared by granulating, drying in a fluidized bed, and then directly compress into tablet (column 7, lines 21 through column 8, lines 1-21).

2. Claims 1-5, 12-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger et al. US 5,204,115.

Olinger teaches a composition comprising about 95% to 99% xylitol, sweetener, e.g., saccharin, acesulfame K, cyclamate, or sucralose; and about 0.1% to about 5% of other

Art Unit: 1615

polyol, e.g., mannitol, lactitol, sorbitol, maltitol, and isomalt (column 6, lines 53 through column 7, lines 16-22). The composition further comprising water soluble additions, e.g., polydextrose containing citric acid (column 7, lines 51-55).

Regarding to claims 3 and 4, the cited reference is silent as to the teaching of spray drying at a temperature of from 120°C to 300°C, however, the rejected claims are the product by process claims, and therefore, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

3. Claims 6-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen et al, Schwarz et al. US 5,958,471, and Mizumoto et al. US 5,576,014.

Virtanen is relied upon for the reasons stated above. The reference differs from the claimed invention by not specifically teaching the ratios of xylitol to mannitol to lactitol.

Schwarz teaches a composition comprising xylitol, other polyol, and additives, e.g., citric acid sweetener, citric acid, or vitamins (column 2, lines 39 through column 3, lines 1-31). The composition is directly suitable for the production of compacted articles, and can be obtained by the process disclosed in column 2, lines 32-63.

The cited references are silent as to the teaching of pharmaceutical additives, e.g., antacid or analgesic agents.

Mizumoto teaches a composition comprising xylitol, lactose, mannitol, glucose, sucrose, or sorbitol (column 6, lines 37-46), analgesics and antacid agents are listed in column 7, lines 62 through column 9, lines 1-43. The composition is then compressed into tablet

Art Unit: 1615

(column 13, lines 16-24). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, use Schwarz's process to prepare Virtanen's xylitol composition with the pharmaceutical agents in view of the teaching of Mizumoto. The reason for this modification is to obtain a direct compressed tablet containing more than 90% xylitol that is useful in pharmaceutical art.

The ratios presented that defined over the properties obtained by the reference, which is silent as to these ratios, have not been evidenced to provide any unusual and/or unexpected results over the applied prior art.

(11) Response to Argument

Claim of Group I (claims 1-9, and 12-20):

The Appellants' evidence of establishing an unobvious (or novel) between the claimed products and the prior art is not persuasive. The argument showing that the granulates of Virtanen and Olinger are inhomogeneous, while the claimed products made by dissolving the xylitol in a solvent is a homogeneous is not persuasive. The Appellant fails to establish that the granulates products of the prior art especially the "inhomogeneous" products, have a detrimental effect upon the desirability of obtaining a directly compressible tableting aid having an improved tablet hardness, friability, and sensory mouthfeel. Appellants' attention is called to Virtanen's column 7, lines 42-46, wherein the product obtained is a free flowing

Art Unit: 1615

compressible composition, which has excellent compressibility; and column 9, lines 40-41, wherein tablets prepared have acceptable mouthfeel, initial hardness, and friability.

Appellants' argument regarding to the process of mixing the sorbitol and xylitol is not persuasive. The rejected claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process". *In re Thorpe*, 77 F2.d 695, 698, 277 USPQ 964, 966 (Fed. Cir. 1985).

Claims of Group II (claims 10 and 11):

Appellants' argument regarding to the cited references do not teach or suggest a xylitol content of more than 90% by weight is not persuasive. Virtanen teaches throughout his reference a direct compressible granulate comprises about 94% to about 98% by weight of xylitol (column 5, lines 38-58; column 6, lines 1-8; and column 8, line 2).

Appellants argue that Virtanen fails to teach a tableting aid produced by dissolving the xylitol in a solvent to obtain a homogeneous solution. Contrary to the Appellants' argument, it is noted that the features upon which Appellants argue (i.e., the homogenous solution) has not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Art Unit: 1615

Appellants argue that Virtanen does not disclose dissolving the xylitol in a solvent, nor introducing both xylitol powder and sorbitol syrup as a single stream. Contrary to the Appellants' arguments, Virtanen teaches sorbitol is added to xylitol in the form of sorbitol syrup, wherein sorbitol is diluted to obtain a solution suits the granulation device (column 7, lines 6-21). The result mixtures are then dried rapidly in a fluidized bed or dryer (column 7, lines 22-25; and example 2). Thus, it would appear that both, sorbitol and xylitol are in solution.

Appellants argue that Olinger fails to teach a tableting aid produced by dissolving the xylitol in a solvent, thus, there is no anticipation of the claimed invention. However, the rejected claims (Group I) are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process". *In re Thorpe*, 77 F.2.d 695, 698, 277 USPQ 964, 966 (Fed. Cir. 1985). Olinger discloses a directly compressible granulate comprising xylitol and other sugars.

Appellants' arguments regarding "no desirability to support alleged combination of Virtanen, Schwarz, and Mizumoto". Appellants argue that Schwarz does not teach the weight ratio of xylitol to sorbitol of Virtanen; and Mizumoto fails to teach dissolving xylitol and sorbitol in solution. In response to the arguments, the Examiner recognizes that obviousness

Art Unit: 1615

can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instance case, Schwarz is relied upon solely for the teaching of an effective drying temperature of between 120°C and 300°C. Mizumoto is relied upon solely for the teaching of antacid and analgesic agents in a compress molding products.

For the above reasons, it is believed that the rejections should be sustained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JOSE G. DEES

SUPERVISORY PATENT EXAMINER

conferee

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600